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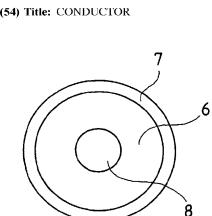
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



(57) Abstract: The invention relates to a conductor, especially a conductor for measuring bio-electric signals occurring in an MRI environment, which comprises an electrically conductive part (6) made of a non-metal material and a sheath part (7) arranged over it. To produce a light and flexible conductor, the impedance of the conductive part (6) is in the range of 5 to 300 kilo-ohm. The sheath part (7) is arranged to endure a required voltage and the conductor comprises a support part (8) which is made of a substantially inelastic material.

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CONDUCTOR

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[0001] The invention relates to a conductor, especially a conductor intended for measuring bio-electric signals occurring in an MRI environment, which comprises an electrically conductive part made of a non-metal material and a sheath part arranged over it.

[0002] EKG measurement refers to measuring the electrical operation of the heart of a living being, such as human being. The measurement is for obtaining information on functional disorders occurring in the heart in different situations. This information obtained through EKG measurement includes the heart rate. At the moment, EKG measurement is a routine procedure in operating theatres and intensive care units in different parts of the world. In EKG measurement, electrodes are placed on the patient's skin, and an EKG monitor measures the voltage difference caused by the operation of the heart and induced between the electrodes. The electric signal generated by the heart is very weak, typically 0.5 mV to 2 mV. This is why EKG measuring instruments are very sensitive and the elimination of external electric interference is very important. Several electrodes are typically connected to the patient, and the configurations formed by them are called connections. Each connection represents a sub-section of the electric operation of the heart. Combining the signals obtained from the connections produces a curve which shows the electric operation of the heart. To obtain an EKG signal, the patient should have at least two electrodes. Generally used EKG connections have 3, 5, 7 or 10 electrodes. The electrodes are typically placed on the patient's chest. The EKG signal is transmitted to the monitor over conductors, which are called EKG conductors. The conductors are typically made of a highly conductive material, such as copper.

[0003] The significance of EKG measurement increases in different areas of treatment in hospitals, since today different examinations are performed even to patients whose condition is quite poor. One area, in which EKG measurement is needed is magnetic resonance imaging. In MRI, a strong static magnetic field and strong radio-frequency pulses are directed to the patient. An image of a required area can be reconstructed on the basis of the signals received from the patient. Today, MRI is also performed on patients in a very poor condition, who are sedated or under anaesthesia. These patients naturally also need monitoring.

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[0004] During MRI, conventional EKG conductors can not be used. The strong radio-frequency pulses, RF pulses, used in MRI may induce in galvanic EKG conductors so strong interference currents that they cause serious burns to the patient. The above-mentioned problem can be solved by keeping the conductors and electrodes as far away from the imaging area as possible, or by using non-metal EKG conductors. There are EKG measuring instruments intended for the magnetic resonance imaging environment, i.e. MRI environment, the conductors of which do not contain metal but some other conductive material. The most typical solutions are conductors made of carbon fibre, in which the conductive part is made of a carbon fibre bundle. In such a solution, the impedance level of the conductor is approximately 200 to 500 ohm, which is not, however, enough, since the RF pulses of MRI devices are so strong that in certain conditions so strong currents may be induced even in this type of conductors that burns are caused to the patient. Another alternative is to use conductors made of a flexible circuit board, to which a higher impedance level can be obtained by connecting several connections in series to one conductor. However, this type of solution is poor in usability and ergonomics, because the circuit boards are stiffer than conductors and their edges are sharp. Conductors containing ferromagnetic metals can not be used in an MRI environment, because the magnet may attract them, and when in the imaging field, they cause interference to the magnetic images.

[0005] It is an object of the invention to provide a conductor, by means of which it is possible to eliminate the drawbacks in prior art. This is achieved by a conductor of the invention. The conductor of the invention is characterized in that the impedance of the conductive part is in the range of 5 to 300 kilo-ohm, that the sheath part is arranged to endure a required voltage, and that the conductor comprises a support part which is made of a substantially inelastic material.

[0006] Above all, the invention provides the advantage that the high impedance effectively prevents the currents caused by RF pulses from being induced in the conductor, whereby the patient's risk of getting burns is substantially less in comparison with the prior art. In spite of the abovementioned matter, the invention provides the further advantage that the conductor is very well suited for EKG measurement, for instance, because the EKG signal passes well through the conductor and EKG monitors can process it, because the input impedance of their preamplifiers is considerably higher

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than in the conductor, typically in the range of giga-ohms. A yet further advantage of the invention is that the conductor of the invention is very flexible and thus well suited for measurement.

[0007] In the following, the invention will be described in greater detail by means of a preferred embodiment shown in the attached drawing in which

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Figure 1 shows a schematic of measuring an EKG curve during magnetic resonance imaging,

Figure 2 shows a cross-sectional view of a conductor of the invention, and

Figure 3 shows an EKG conductor set formed of conductors of the invention.

[0008] Figure 1 shows in general a situation in which an EKG curve is measured of a patient 1 during magnetic resonance imaging. Reference numeral 2 in Figure 1 marks the MRI device, reference numerals 3 mark EKG conductors and reference numeral 4 marks a monitor for examining the EKG curve. The EKG conductors are attached to the patient by means of electrodes 5 arranged at the ends of the conductors. An EKG conductor set of three conductors forming an entity is formed by the EKG conductors 3, of which there are three in the example of the figure.

[0009] Figure 2 shows a conductor of the invention. The invention relates especially to a conductor intended for measuring bio-electric signals occurring in an MRI environment, which has an electrically conductive part 6 made of a non-metal material and a sheath part 7 arranged over it. The impedance of the conductive part 6 is in the range of 5 to 300 kilo-ohm. The sheath part 6 is arranged to endure a required voltage, for instance 5 kV, in compliance with the standard ANSI/AAMI EC53-1995 Section 4.5.1. It has been detected that the sheath part should endure at least a 3-kV voltage, preferably a 5-kV voltage, and most preferably at least a 7-kV voltage. The conductor also comprises a support part 8 which is made of a substantially inelastic material. A substantially inelastic material refers herein to a material which in a load of 50 Newton is allowed to stretch 30%/m. A material which stretches 5%/m is preferable, and the best material is one which stretches 1%/m.

[0010] The high impedance effectively prevents the currents caused by RF pulses from inducing in the conductors and thus substantially

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reduces the risk for burns in comparison with the prior art. So that the RF pulses would not induce currents in the conductors, but it would still be possible to measure the EKG signal, the impedance of the conductors should be in the range of 5 to 300 kilo-ohm. A preferable impedance level is 20 to 100 kilo-ohm and the best impedance level is 40 to 80 kilo-ohm.

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[0011] A conductor set having three conductors, for instance, can be formed of conductors of the invention, and the conductor set can be used for measuring a 3-connection EKG during magnetic resonance imaging. A schematic of the above-mentioned conductor set is shown in Figure 3. The conductive part 6 of the conductors in the conductor set is made of a conductive non-metal material having a high impedance, approximately 60 kilo-ohm/conductor, for instance. The conductive non-metal material can be any suitable material, for instance a silicone compound to which carbon particles have been added evenly to produce conductivity. The impedance level of the conductor is determined by the length and diameter of the conductor. The impedance level can be optimized by adjusting the diameter and length of the conductor. If the length of each conductor in the conductor set is selected to be 6.5 m, the diameter of the conductive part of the conductor becomes approximately 2 mm. This diameter includes the support part 8 which is arranged in the middle of the conductor and which can be any substantially inelastic material as described above, for instance a bundle made up of Kevlar fibres. Kevlar fibres make the conductor substantially inelastic. The support part can also be located elsewhere than on the centre axis of the conductor, for instance on the edge of the conductor. With the abovementioned dimensions, the impedance of the conductor becomes approximately 60 kilo-ohm. If the length of the conductor is increased, its impedance increases correspondingly. If the diameter of the conductive part 6 of the conductor is made smaller, the impedance of the conductor increases correspondingly.

[0012] Conductors made of conductive silicone have been tested and compared with prior-art carbon fibre conductors in an MRI environment. In the comparison, both conductors were connected to the imaging object and during the imaging, the voltage induced between two conductors was measured. The voltage of the carbon fibre conductor was 93 V p-p, whereas the voltage of the conductor made of conductive silicone was 2 V p-p. From

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this, it can be directly deduced that substantially fewer currents were induced in the conductors made of the higher-impedance conductive silicone.

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[0013] A sheath part 7, which can be any suitable bio-compatible, i.e. non-toxic or non-allergenic, material, is pressed over the conductive material of the conductor of the invention. The material should also have certain voltage endurance properties as described above. Polyurethane is an example of a suitable material. A solution combining conductive silicone and a polyurethane sheath makes the conductor light, flexible and as usable as prior-art galvanic EKG conductors. The conductor of the invention is also suited for use in CT examinations, because the material used in it does not show in an X-ray examination. A CT (computerized tomography) examination is an imaging method where a patient is photographed by means of X-rays and the received signals are used to construct an axial image of the required object.

[0014] The embodiment shown in Figure 3 also shows clearly the electrodes 5 arranged at the ends of the conductor, by means of which the conductors are attached to the patient. The electrodes are made up of jaw parts 5a made of a non-metal conductive hard material and correspondingly of a second jaw part 5b, which can be made of a suitably coloured plastic material, whereby a mechanical contact is made possible and the identification of the electrodes is easy. The jaw part 5a can, for instance, be made of a suitable plastic material to which carbon is added. One end of the conductor set is naturally equipped with an appropriate connector 9, by means of which the conductor set can be connected to a monitor 4, for instance, shown in Figure 1.

[0015] The embodiment described above is in no way intended to limit the invention, but the invention can be modified freely within the scope of the claims. Therefore, it is clear that the conductor of the invention, its details, or the solutions formed by means of the conductor need not necessarily be exactly as described in the figures, and other solutions are also possible. For instance, a layer preventing the generation of static electricity can be formed over the conductor.

CLAIMS

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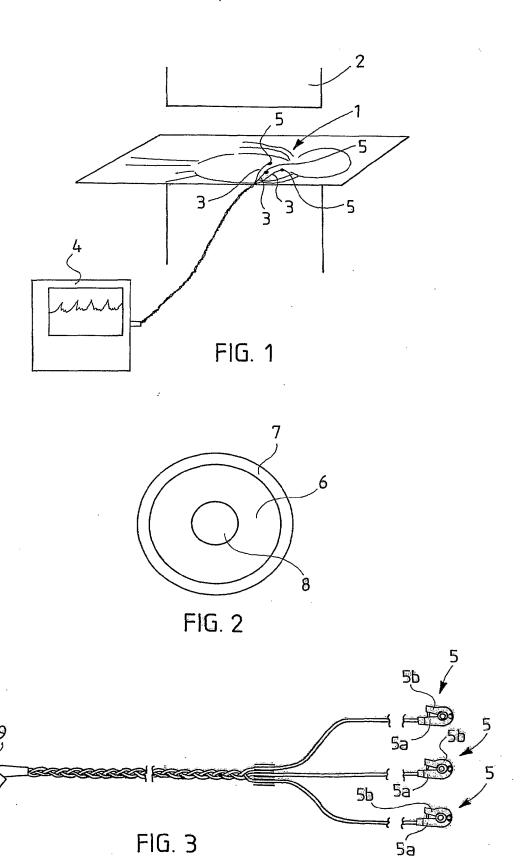
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- 1. A conductor, especially a conductor for measuring bio-electric signals occurring in an MRI environment, which comprises an electrically conductive part (6) made of a non-metal material and a sheath part (7) arranged over it, **characterized** in that the impedance of the conductive part (6) is in the range of 5 to 300 kilo-ohm, that the sheath part (7) is arranged to endure a required voltage, and that the conductor comprises a support part (8) which is made of a substantially inelastic material.
- 2. A conductor as claimed in claim 1, **characterized** in that the impedance of the conductive part (6) is in the range of 20 to 100 kilo-ohm.
- 3. A conductor as claimed in claim 2, **characterized** in that the impedance of the conductive part (6) is in the range of 40 to 80 kilo-ohm.
- 4. A conductor as claimed in claim 1, **characterized** in that the conductive part (6) is made of a conductive silicone compound.
- 5. A conductor as claimed in claim 4, **c** h a racterized in that carbon particles have been added evenly to the silicone compound.
- 6. A conductor as claimed in claim 1, **characterized** in that the sheath part (7) is made of polyurethane.
- 7. A conductor as claimed in claim 1, **characterized** in that the support part (8) is arranged on the centre axis of the conductor.
- 8. A conductor as claimed in claim 1 or 7, **characterized** in that the support part (8) is made of Kevlar fibres.
- 9. A conductor as claimed in claim 1, **characterized** in that the conductor is equipped with an electrode (5) which is at least partly made of a conductive hard non-metal material.
- 10. A conductor as claimed in claim 9, **characterized** in that the conductive non-metal material is a plastic material with carbon added to it.



INTERNATIONAL SEARCH REPORT

International application No. PCT/FI 01/00582

A. CLASSIFICATION OF SUBJECT MATTER IPC7: A61B 5/04, H01B 1/04 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC7: A61B, H01B, H01C Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched SE,DK,FI,NO classes as above Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. A DE 19637472 A1 (SCHNIER ELEKTROSTATIK GMBH ET AL), 1-10 26 March 1998 (26.03.98), figure 1, abstract Α US 4970488 A (T. HORIIKE ET AL), 13 November 1990 1-10 (13.11.90), column 3, line 46 - line 68, figure 2 A US 5782241 A (J. FELBLINGER ET AL), 21 July 1998 1-10 (21.07.98), figures 1,3, abstract P,A DE 19922999 A1 (KENDALL-MEDIZINISCHE ERZEUGNISSE -1-10 GMBH), 23 November 2000 (23.11.00), abstract, figure Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination document referring to an oral disclosure, use, exhibition or other means being obvious to a person skilled in the art document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 0 5 -10- 2001 <u> 3 October 2001</u> Name and mailing address of the ISA/ Authorized officer Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Vilho Juvonen / MRo Facsimile No. +46 8 666 02 86 Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

03/09/01

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